~~ADD~~ HFI-35 5/28/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

M915N

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
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P.O. Box 3012
Bothell WA 98041-3012

Telephone: 206-486-8788
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May 14, 1997

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-20

WARNING LETTER

Galen Clayson, Owner
Cedar Arch Dairy
600 North 710 East
Firth, Idaho 83236

Dear Mr. Clayson:

An investigation at your dairy operation located at Firth, Idaho, conducted on April 29-30, 1997, confirmed that you offered an animal for sale for food in violation of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On December 6, 1996, you sold a dairy cow identified with [redacted] tag # 9774 for slaughter as human food. USDA analysis of tissue samples collected from that animal identified the presence of 1.60 ppm and 3.50 ppm sulfadimethoxine in the liver and muscle respectively. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(D).

Our investigation also found that you hold animals under conditions which allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for, a) maintaining medication/treatment records which identify the animal, the dosage administered, and drug pre-slaughter withdrawal time; b) ensuring drug label directions are followed; c) and to review treatment records prior to offering an animal for slaughter to assure drugs are used as directed. Foods from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand of sulfadimethoxine that your dairy uses on cows within the meaning of Section

501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug at higher than labeled doses and failure to follow pre-slaughter withdrawal time causes the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step being taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Richard S. Andros, Compliance Officer, at the above address.

Sincerely yours,

Roger L. Lowell
District Director